United States Department of Agriculture
Agricultural Marketing Service, Science & Technology
Microbiological Data Program

SOP No.: MDP-ADMIN-06A		Page 1 of 6
Title: USDA/AMS Quality Assurance Unit (QAU)		
Revision: Original	Replaces: N/A	Effective: 08/15/03

1. Purpose:

To establish requirements for the USDA/AMS Microbiological Data Program (MDP) quality assurance unit (QAU).

2. Scope:

This standard operating procedure (SOP) shall be followed by the USDA/AMS MDP QAU located in the Monitoring Programs Office (MPO), Manassas, VA.

3. Outline of Procedure:

5.1 Description
5.2 Files and Records
5.3 Reports
5.4 Proficiency Testing (PT) Program
5.5 Technical Advisory Committee (TAC)
5.6 SOPs

4. References:

- MDP Federal/State Meeting, Arlington, VA, May 15-16, 2003
- U.S. EPA, Quality Assurance Unit, 40 CFR part 160.35, July 1, 1999

5. Specific Procedures:

5.1 Description

5.1.1. USDA/AMS shall have a quality assurance unit (QAU) which shall be responsible for monitoring overall quality assurance of the program. The QAU shall be

responsible for assuring USDA/AMS management that facilities, equipment, personnel, methods, practices, records, and controls of the program are in conformance with the plans and SOPs issued by USDA/AMS.

5.1.2 The QAU shall be entirely separate from and independent of participant personnel engaged in the technical direction and/or conduct of the microbiological studies. The QAU shall report directly to the USDA/AMS Administrative Director.

5.1.3 The QAU may consist of one or more personnel of suitable qualifications.

5.1.4 The QAU shall maintain records appropriate to MDP studies.

5.2 Files and Records

5.2.1 The QAU shall maintain a copy of the MDP Annual, Semi-annual, or quarterly plan including the schedule of samples, organisms, and commodities to be tested.

5.2.2 The QAU shall maintain copies of special project status reports prepared by USDA/AMS liaison microbiologists.

5.2.3 The QAU shall maintain copies of all laboratory QA status and yearly audit reports.

5.2.4 The QAU shall maintain a schedule of USDA/AMS sampling and laboratory reviews and report submissions. This shall include the dates reviews were made and the dates findings were reported to appropriate individuals (refer to section 5.1.d.3 of this SOP).

5.2.5 The QAU shall maintain copies of all USDA/AMS sampling and laboratory review reports.

5.2.6 The QAU shall maintain copies of all validation data review reports.

5.2.7 The QAU shall maintain copies of all USDA/AMS SOPs, including sampling, laboratory, and USDA/AMS internal SOPs.

5.2.8 The QAU shall maintain copies of authorizations for deviations from the USDA/AMS SOPs.

5.2.9 The QAU shall monitor the proficiency of MDP laboratories.

5.2.10 QA documents shall be maintained in a secure manner with reasonable environmental protection from deterioration for the life of the program.

5.3 Reports

The QAU shall review all validation study reports to ensure that consistent policies are applied and shall make recommendations based on findings.

5.4 Proficiency Testing (PT) Program

In consultation with the Technical Director, the QAU shall oversee the PT, or check sample, program.

5.4.1 The USDA/AMS QAU shall ensure that check samples are delivered on schedule, reports are prepared in a timely fashion and distributed to appropriate individuals. Distribution shall include the Technical Director and participating laboratory TPMs and QAUs.

5.4.2 The QAU shall review check sample reports and submit comments on overall performance to the Technical Director. Comments shall include recommendations as necessary to improve performance.

5.5 Technical Advisory Committee (TAC)

The USDA/AMS QAU shall serve as liaison to the USDA/AMS TAC. The committee shall be comprised of selected members of participating laboratories and shall address program technical and QA issues/concerns.

5.6 SOPs

5.6.1 The QAU shall maintain the USDA/AMS MDP SOPs. Refer to MDP-ADMIN-07, section 5.3, for specific details.

5.6.2 The QAU shall ensure that any authorization for deviations from approved program plans or USDA/AMS MDP SOPs does not compromise integrity of data. The QAU shall ensure that precise and technically accurate documentation of such errors/deviations is maintained.

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Approved by: Grace Hall, Chairperson Date
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- Established requirements for USDA/AMS MDP QAU